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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IMPRIMIS PHARMACEUTICALS,
INC, a Delaware corporation,

Plaintiff,

vs.

THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA, a
California corporation; and URIGEN
PHARMACEUTICALS, INC., a
Delaware corporation,

Defendants.

Case No.: **'16CV1063 BTM DHB**

**COMPLAINT FOR DECLARATORY
JUDGMENT OF PATENT
INVALIDITY; DEMAND FOR JURY
TRIAL**

1 Plaintiff Imprimis Pharmaceuticals, Inc. (hereinafter “plaintiff” or
2 “Imprimis”), pursuant to Fed. R. Civ. P. 8(a), alleges upon knowledge as to itself
3 and its own actions, and upon information and belief as to all other matters, against
4 defendants The Regents of the University of California and Urigen
5 Pharmaceuticals, Inc., as follows:

6 THE PARTIES

7 1. Imprimis is a corporation organized and existing under the laws of the
8 State of Delaware and has as its principal place of business and is doing business in
9 the County of San Diego, State of California.

10 2. Defendant The Regents of the University of California (“the
11 Regents”) is a public corporation. It is the assignee of United States Patent
12 7,414,039 (the “‘039 Patent”) entitled “Interstitial Therapy for Immediate
13 Symptom Relief and Chronic Therapy in Interstitial Cystitis,” which issued on
14 August 19, 2008.

15 3. Defendant Urigen Pharmaceuticals, Inc. (“Urigen”), is a corporation
16 organized and existing under the laws of the State of Delaware and is doing
17 business in the State of California. Pursuant to a valid written contract, Urigen is
18 the sublicensee of Regents of the entire right, title, and interest in the ‘039 Patent.

19 JURISDICTION AND VENUE

20 4. This Court has jurisdiction over the subject matter of this action
21 pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims
22 arising under Patent Act, 35 U.S.C. § 1, *et seq.*

23 5. This Court has jurisdiction to provide declaratory judgment that the
24 ‘039 Patent is invalid pursuant to 28 U.S.C. §§ 2201 and 2202, arising from the
25 case of actual controversy described herein.

26 6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and
27 1400(b).
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1 7. This Court has personal jurisdiction over defendants. Both the
2 Regents and Urigen have purposefully availed themselves of the privilege of
3 conducting activities in the State of California and this District.

4 8. The Regents is a California corporation headquartered in this state and
5 has continuous and systematic business contacts in this District.

6 9. On information and belief, Urigen has continuous and systematic
7 business contacts in the State of California and this District and regularly conducts
8 and has conducted business in the State of California and this District.

9 EXISTENCE OF ACTUAL CONTROVERSY

10 10. On or about October 24, 2014, Imprimis and Urigen entered into that
11 certain License Agreement, a true and correct copy of which accompanies this
12 complaint as Exhibit 1 and whose contents are incorporated herein by this
13 reference as though fully set forth.

14 11. The License Agreement provided for, among other things, Imprimis to
15 exploit commercially certain rights Urigen claimed under sublicense under the
16 ‘039 Patent, a true and correct copy of which accompanies this complaint as
17 Exhibit 2 and whose contents are incorporated herein by this reference as though
18 fully set forth. The inventions disclosed by the ‘039 Patent are useful in the field
19 of prevention or treatment of disorders of the lower urinary tract (defined as the
20 bladder, prostate, urethra, and related conditions).

21 12. In exchange for such rights, Imprimis promised to pay Urigen
22 royalties on U.S. sales of products covered by those patent rights and to commit \$2
23 million on commercialization efforts through a dedicated national sales campaign
24 intended to maximize sales of those products. Urigen assigned to Imprimis the
25 right to convert the non-exclusive license to an exclusive license (with the right to
26 grant sublicenses through multiple tiers) on certain conditions. Imprimis converted
27 the then non-exclusive license to an exclusive license on April 24, 2015.
28

1 13. The License Agreement embodied certain representations and
2 warranties. These included, *inter alia*, Urigen’s lack of awareness of any
3 “widespread or commercial scale infringement or misappropriation” of the licensed
4 patent rights by any third parties and, implicitly, the validity of the ‘039 Patent
5 itself and lack of awareness of any undisclosed prior art that might invalidate the
6 ‘039 Patent outright.

7 14. Imprimis invested significant money, time, effort, and other resources
8 in a dedicated national sales campaign pursuant to terms of the License Agreement.
9 Imprimis built a marketing program, hired senior experienced urology field
10 representatives, attended numerous urology meetings across the U.S., engaged
11 leading urologists and uro-gynecologists as experts, and engaged in many other
12 activities designed to help ensure the success of the efforts to which both parties
13 committed pursuant to the License Agreement.

14 15. Before and during the time of the parties’ negotiation of the License
15 Agreement, Urigen knew of, but did not disclose to Imprimis, widespread
16 infringements of the ‘039 Patent. Within the last year, Imprimis learned of the size
17 and scale of the infringements described hereinabove. There were hundreds
18 (possibly over a thousand) medical professionals across the U.S. infringing the
19 ‘039 Patent that Urigen had licensed to Imprimis, in cities large and small, and in
20 every State in which Imprimis was attempting to market its products pursuant to
21 the License Agreement. (The damages that flowed from Urigen’s wrongdoing are
22 the subject of a current state court action: San Diego Superior Court case number
23 37-2015-00040800.)

24 16. Urigen concealed from Imprimis the existence of prior art which
25 anticipated the claims of the ‘039 Patent. Imprimis’ recent investigation revealed
26 at least three instances of prior art described in printed publications predating the
27 invention described by the ‘039 Patent by more than one year before the U.S.
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1 patent application was filed. The '039 Patent was filed on January 27, 2005. Ex.

2 2. Each of the three following publications predated that filing by several years:

3 a. U.S. Patent 8,178,516, with a priority date of June
4 30, 1992, teaches heparin and lidocaine
5 combination to treat interstitial cystitis (section (x),
6 col. 23, lines 41 and 49), a true and correct copy of
7 which accompanies this complaint as Exhibit 3 and
8 whose contents are incorporated herein by this
9 reference as though fully set forth;

10
11 b. Kusner *et al.*, Urology, 57 (6 Supplement 1), p.
12 129 (June 2001), describes medications that
13 include 0.9% lidocaine and 10,000 units of heparin
14 to treat interstitial cystitis; a true and correct copy
15 of which accompanies this complaint as Exhibit 4
16 and whose contents are incorporated herein by this
17 reference as though fully set forth; and

18
19 c. Nickel, Review of Urology (2002, Summer Issue;
20 4(3), pp. 112-121, teaches treatments of interstitial
21 cystitis with heparinoids and alkalized lidocaine, a
22 true and correct copy of which accompanies this
23 complaint as Exhibit 5 and whose contents are
24 incorporated herein by this reference as though
25 fully set forth.

26 17. An immediate, real, and justiciable controversy exists between
27 Imprimis and Urigen with respect to the validity of the claims of the '039 Patent.
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COUNT I

Declaratory Judgment of Invalidity of U.S. Patent No. 7,414,039

(Failure to Enforce Patent Rights)

(Against All Defendants)

18. Imprimis realleges and incorporates by reference as though fully set forth the preceding paragraphs 1 through 17.

19. Each of the claims of the '039 Patent is invalid because Urigen has failed to comply with the requirements of Title 35 of the United States Code §§ 1, *et seq.*, including, *inter alia*, § 282.

20. Based on the foregoing, Imprimis seeks a declaratory judgment that each claim of the '039 Patent is invalid.

COUNT II

Declaratory Judgment of Invalidity of U.S. Patent No. 7,414,039

(Anticipation by Prior Art)

(Against All Defendants)

21. Imprimis realleges and incorporates by reference as though fully set forth the preceding paragraphs 1 through 20.

22. Each of the claims of the '039 Patent are invalid because Urigen has failed to comply with the requirements of Title 35 of the United States Code §§ 1, *et seq.*, including, *inter alia*, §§ 102, 103, and/or 112.

23. Based on the foregoing, Imprimis seeks a declaratory judgment that each claim of the '039 Patent is invalid.

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1. Judgment declaring each of the claims of the '039 Patent invalid;
2. An award of attorneys' fees, costs, and expenses incurred in this action due to an exceptional case and in overall interest of justice pursuant to, *inter alia*, 35 U.S.C. § 285; and
3. Such other and further relief as this Court deems just and proper.

LAWTON LAW FIRM

By: s/Dan Lawton
 Dan Lawton
 Attorneys for Plaintiff Imprimis
 Pharmaceuticals, Inc.